510 (k) Summary of Safety and Effectiveness

K061752

Date Summary Prepared:	June 20, 2006
Submitter Information:	Spinal USA 644 Lakeland East Drive Suite A Flowood, MS 39047
Contact Name: Phone: Fax: E-mail:	Jeffrey Johnson 601-420-4244 601-420-5501 jeff@spinalusa.com
Device Trade Name:	Spinal USA VBR System
Common Name:	Vertebral Body Replacement
Regulatory Number: Classification: Product Code:	888.3060 Class II MQP

AUG 16 2006

INTENDED USE:
The Spinal USA VBR System is intended for use in the thoracic and/or thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The Spinal USA VBR System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column. The Spinal USA VBR System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). In addition, the Spinal USA VBR System is intended for use with bone graft.

DEVICE DESCRIPTION:
The Spinal USA VBR System is a vertebral body replacement device that is implanted into the vertebral body space to improve stability of the spine. The system consists of a straight, curved, round, and trapezoidal implants. The various implants vary in lengths, widths, and heights to meet the individual patient anatomy. All components are made from medical grade titanium or titanium alloy described by such standards as ASTM F136 or ISO5832-3. The products are supplied clean and "NON-STERILE".

EQUIVALENT DEVICE:
Testing in accordance with ASTM F2077-03 "Test Methods for Intervertebral Body Fusion Devices" of the Spinal USA VBR System demonstrates that the device is substantially equivalent to the Novel VBR Spinal System (K042201), Lanx VBR System (K052384), Depuy Acromed Stackable Cage (K990148), Quantum VBR Quantum Orthopedics(K050449), PEEK Tetris Signus Medical (K031757), CO VBR Scient'X(K050348), Ellys and Aurys VBR Scient'X (K033109).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2006

Spinal USA
% Mr. Jeffrey Johnson
Manager, Regulatory Affairs
644 Lakeland East Drive, Suite A
Flowood, Mississippi 39232

Re: K061752
Trade/Device Name: Spinal USA VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: June 20, 2006
Received: June 21, 2006

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This

letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devicesd
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061752

Indications for Use

510(k) Number (if known): _____

Device Name: Spinal USA VBR System

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruens

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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